

PEC UPDATE

VOLUME 96-07

15 APRIL 1996

DOD PharmacoEconomic Center, 2107 17th Street, Bldg 4197, Ft Sam Houston, TX 78234-5036 DSN: 471-4311; Commercial: (210) 221-4311: FAX Extension: 4314

E-Mail: hscphaec@smtplink.hcssa.amedd.army.mil HomePage: http://www.ha.osd.mil/hppec2.html#Start

ISSUE HIGHLIGHTS

Update of PEC Disease State Reviews

- 1 -

Request for Diabetes Information

- 2 -

From the Mailbag.....
PEC Q & A

- 2 -

FDA-Approved Drugs for Unlabeled Indications

- 2 -

CEPRP Publishes Cholecystectomy Quality Management Review

- 3 -

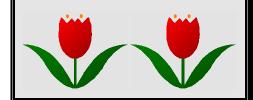
FYI: Availability of Indinavir

- 3 -

Tri-Service Formulary Quick Reference Guide

- 4 -

Spring is in the Sir!



Update of PEC Disease State Reviews

The PEC recently re-evaluated the list of disease states scheduled for review. The current PEC schedule of disease state reviews is listed below. A specific time line has not been established for many of these disease states since we will be working with the Defense Personnel Support Center (DPSC) on Best Value procurements for medications used in these disease states. Vulvovaginal candidiasis is the first disease state analysis to be included in the Best Value procurement process. The PEC and DPSC will jointly determine if a Best Value procurement is appropriate for a particular disease state analysis. The PEC will inform medical treatment facilities of any changes to this schedule in future Updates. Manufacturers will be notified of a disease state review by DPSC and the PEC through the Information Synopsis published in the *Commerce Business Daily*.

Disease State	Action
Vulvovaginal candidiasis	Request for Proposal sent out by DPSC, March 1996
Asthma	Consultant panel convened, modifications in progress
Migraine headache prophylaxis	Consultant panel convened, modifications in progress
Benign prostatic hyperplasia	Near completion
Hepatitis A vaccine	Near completion
Type II diabetes mellitus	Preliminary literature review in progress
Acid-peptic disorders • Helicobacter pylori infection (duodenal ulcer/gastric ulcer) • Gastroesophageal reflux disease	Preliminary literature review in progress To be announced
Major depression	To be announced

Request for Diabetes Information

The PEC is starting to review data and develop a pharmacoeconomic model for the treatment of non-insulin-dependent diabetes mellitus To help us develop the most (NIDDM). appropriate model, we would like to hear how practitioners in the field are managing NIDDM patients. The PEC is interested in any treatment protocols for NIDDM manage-ment, results of drug usage evaluations of NIDDM therapy, data from NIDDM outcomes studies, innovative patient education programs or moni-toring tools, or any other information related to the treatment of NIDDM that you are willing to share. If you have any questions, please contact LTC Rick Downs at the PEC at (210) 221-4311.

From the Mailbag.....
PEC Q & A

What is the Tri-Service Formulary (TSF) and what does it mean if a drug is included on the TSF?

The Tri-Service Formulary was developed to establish a basic, clinically nonrestrictive formulary to serve as the basis for a consistent and equitable pharmaceutical benefit for all eligible patients in the Department of Defense. The initial TSF was approved in November 1993 by the Assistant Secretary of Defense (Health Affairs) and contained medications that are well-accepted as standard therapy. The PharmacoEconomic Center (PEC) recommends additions or deletions to the TSF based on pharmacoeconomic analyses of disease states.

TSF medications form the foundation for individual military medial treatment facility (MTF) formularies. An MTF can supplement its formulary with additional medications to meet the

needs of their patients. However, the TSF medications must be readily available to all beneficiaries at all MTFs, thus providing a consistent core pharmacy benefit and assisting continuity of care. Additionally, the availability of TSF medications at all MTFs allows practitioners reassigned to other military facilities to remain familiar with a core group of medications.

The Tri-Service Formulary Quick Reference Guide included on page 4 of this Update provides the most current list of TSF medications.

FDA-Approved Drugs for Unlabeled Indications



Physicians have always been free to prescribe an FDA-approved drug for unlabeled indications based on clinical judgment in the context of the prevailing standards of care. It is estimated that some 40% to 60% of all prescriptions are for uses the FDA has not approved.¹

In the analysis of any given disease state, the PEC must consider all relevant drug treatment options to determine the most cost-effective treatment strategies. Many drugs have sufficient scientific evidence to support their use in a given disease state, and their use is well recognized and accepted by physicians, even though the drugs may not have an FDA approval for a particular disease For example, N-acetylcysteine was the treatment of choice, indeed the only treatment, for acetaminophen overdose for many years before it carried an FDA indication. Other examples include aspirin for post-myocardial infarction prophylaxis and alpha-adrenergic blockers, like prazosin, for benign prostatic hyperplasia.

For these reasons, the PEC will endorse the use of FDA-approved drugs for unlabeled indications where appropriate. Additionally, such drugs will

be included in disease state analyses, which may result in their selection for the Tri-Service Formulary and promotion as preferred treatment for a given disease state.

1. Associated Press. Unapproved use of drugs mulled. In: AP Online. FaxBack FaxNews 1996 Jan 16; Document no. 3564.



CEPRP Publishes Cholecystectomy Quality Management Review

The Department of Defense (DOD) Civilian External Peer Review Program (CEPRP) recently published the results of a retrospective evaluation of practice patterns and policies for cholecystectomies performed in 95 military medical treatment facilities (MTFs).¹

The study was conducted in two phases. The introductory phase was conducted from 1990 to 1992 to assess the safety of laparoscopic cholecystectomy. This review confirmed the safety of the procedure with clinical outcomes found in the Military Health Services System (MHSS) comparable to those reported in civilian studies.

The second phase of the study was conducted from January 1993 through May 1994 to assess laparoscopic cholecystectomy in the MHSS during a 'steady state' period. The percentage of laparoscopic cholecystectomies performed in this phase of the study increased from 65.9% (introductory phase) to 87.3%. Despite the expanded use of this procedure in higher risk patients, the overall complication rate was unchanged.

The Quality Management Review evaluates the processes of care, clinical outcomes, and resource utilization associated with the care of patients undergoing cholecystectomy to develop Clinical Practice Profiles (CPPs) to identify "Best Clinical Practice".

Models were developed to identify individual processes of care and MTF policies which had influence on outcome severity and resource cost units. Of particular interest to the PEC is the use of preoperative antibiotics. Preoperative first gener-ation cephalosporins were associated with better outcomes and lower resource utilization than the model predicted. The MTFs with the best CPPs used first generation cephalosporins more frequently than DOD as a whole. Cefazolin, a first generation cephalosporin, is the recommended prophylactic agent for biliary tract surgery.²

Overall the review found 88% of cholecystectomies performed in military hospitals had no significant complications. However, the cost of treatment varied substantially across the MTFs with MTF policies significantly affecting the cost of care.

For additional information about the Cholecystectomy Quality Management Review, please contact FMAS Corporation at (301) 984-6180.

References:

- Crawford RS, Stahl SM. An evaluation of care, outcomes, and resource utilization associated with cholecystectomy in military treatment facilities January 1993-May 1994. Rockville: FMAS Corporation, Department of Defense Civilian External Peer Review Program; 1995 Dec. Ad hoc 159.011.
- 2. Anonymous. Antimicrobial prophylaxis in surgery. Med Lett Drugs Ther 1995;37(957): 79-82.



FYI: Availability of Indinavir

Indinavir (Crixivan® - Merck), a new protease inhibitor for the treatment of HIV infection, was approved by the Food and Drug Administration in March 1996. Limited supplies of the drug will be available initially. Crixivan® can be ordered for individual patients by calling Michael Skoien, Merck Senior Customer Manager, at (215) 652-5039.

Tri-Service Formulary Quick Reference Guide

Antimicrobials / Antifungals

- *amoxicillin oral suspension and caps
- *Bactrim™/Septra® susp and tabs
- *dicloxacillin oral
- *doxycycline 100 mg caps
- *erythromycin oral suspension and tabs or caps
- *erythromycin/sulfisoxazole susp
- *griseofulvin 125 mg tabs
- *isoniazid 300 mg tabs
- *metronidazole 250 mg tabs
- *nystatin oral suspension
- *penicillin VK susp and 250 mg tabs
- *rifampin 300 mg caps
- *tetracycline 250 mg caps

Antibiotics-EENT

- *Cortisporin® Otic Suspension
- *gentamicin ophth. soln. 0.3%
- *Neosporin® Ophth. Solution
- *sulfacetamide ophth. oint. 10%

Antivirals

acyclovir 200 mg caps

Anthelmintics

mebendazole 100 mg chew tabs

Antiulcer Drugs

- *amoxicillin oral
- *bismuth subsalicylate 262 mg tabs
- *metronidazole 250 mg tabs
- *tetracycline 250 mg caps

GERD Agents

cisapride 20 mg tabs omeprazole 20 mg caps

Other GI Agents

- *dicyclomine tabs or caps
- *Donnatal® tabs
- *sulfasalazine 500 mg tabs

Anti-diarrheals

*loperamide 2 mg tabs or caps

Genitourinary Agents

- *oxybutynin 5 mg tabs
- *phenazopyridine 100 mg tabs

Gout Agents

- *allopurinol tabs
- *probenecid 500 mg tabs

Muscle Relaxants

- *diazepam 5 mg tabs
- *methocarbamol 500 mg tabs

Nasal Corticosteroids

*beclomethasone nasal inhaler

Oral Corticosteroids

- *prednisone 5 mg tabs
- *prednisone 20 mg tabs

Asthma Agents

- *albuterol oral inhaler
- *beclomethasone oral inhaler
- *terbutaline 5 mg tabs

Antihistamines / Decongestants

- *Actifed® tabs
- *chlorpheniramine 4 mg tabs
- *chlorpheniramine syrup
- *Dimetapp® Elixir
- *Dimetapp® Extentabs
- *diphenhydramine caps
- *diphenhydramine syrup
- *hydroxyzine syrup
- *hydroxyzine tabs
- *oxymetazoline nasal spray
- *pseudoephedrine 30 mg tabs

Anticonvulsants

Dilantin® Infatabs 50 mg

Dilantin® Kapseals 100 mg

- *phenobarbital elixir 20 mg/5 mL
- *phenobarbital 30 mg tabs
- *primidone 250 mg tabs
- †Tegretol® 200 mg tabs

Anticoagulants

warfarin 5 mg tabs

Diuretics

- *furosemide 40 mg tabs
- *hydrochlorothiazide tabs
- *Maxzide® tabs
- *spironolactone 25 mg tabs

Vasodilators

*isosorbide dinitrate 10 mg tabs nitroglycerin sublingual tabs

Lipid Lowering Agents

colestipol powder

*niacin tabs

pravastatin 10 mg, 20 mg, 40 mg tabs

Hypotensive / Cardiac Drugs

- *atenolol tabs
- *clonidine tabs
- †Lanoxin® 0.25 mg tabs

lisinopril tabs

- *propranolol 10 & 40 mg tabs
- *quinidine gluconate 324 mg tabs
- *quinidine sulfate tabs
- terazosin tabs
- *verapamil long-acting tabs

Diabetic Agents

*human insulin, regular & NPH

Electrolyte Replacement

*potassium chloride slow release tabs or caps

NSAIDS / Analgesics

- *acetaminophen drops, elixir, and 325 mg tabs
- *aspirin, enteric-coated 325 mg tabs
- *ibuprofen susp and 400 mg tabs
- *indomethacin 25 mg caps
- *Tylenol #3® tabs

Migraine Agents

- *Cafergot® tabs
- *Fiorinal® tabs
- *Midrin® caps

Attention Deficit / Narcoleps y Agents

- *methylphenidate 10 mg tabs
- *methylphenidate sustained release 20 mg tabs

Contraceptives

LoOvral®

*Norinyl 1+50®, Ortho-Novum 1/50®

*Ortho-Novum 1/35®, Norinyl 1+35® Ortho-Novum 7/7/7®

Ovral®

Triphasil®/Tri-Levlen®

Estrogens / Progestins

conjugated estrogens 0.625 mg tabs conjugated estrogen vaginal cream *medroxyprogesterone 10 mg tabs

Thyroid / Antithyroid Agents

*propylthiouracil 50 mg tabs †Synthroid® 100 mcg (0.1 mg) tabs

Topical Agents

*bacitracin ointment

*hydrocortisone 1% cream

Sebutone® shampoo
*Selsun® shampoo

Vitamins & Minerals

*ferrous sulfate concentrated soln. 125 mg/mL

*ferrous sulfate 325 mg tabs *pyridoxine 50 mg tabs

Miotics

*pilocarpine ophth. solution

Miscellaneous

insect sting kit

*generic products are available †DMSB sole source item

Brand names are included for example only and are not meant to imply the recommendation of a specific product except for those products designated as sole source items by the Defense Medical Standardization Board.

Updated October 1995